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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,780	03/29/2004	Yiwen Tang	50623.280	5001

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EXAMINER	
FISHER, ABIGAIL L	
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4173	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,780	TANG ET AL.	
	Examiner	Art Unit	
	Abigail Fisher	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *12 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 15-24 and 26-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9 Sheets*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-27 are pending.

Election/Restrictions

Applicant's election without traverse of poly(alkylene glycol) (as the biocompatible polymeric moiety), poly(caprolactone) (as the species of the second polymer, biologically degradable polymer, and the structural polymeric moiety), and poly(ethylene-glycol)-block-copoly(caprolactone) (as the block co-polymer) in the replies filed on August 10 2007 and October 26 2007 is acknowledged.

Claims 1-27 are pending in the application, with claims 12 and 25 having been withdrawn as drawn to a non-elected species. Accordingly, claims 1-11, 13-24, and 26-27 are being examined on the merits herein.

Information Disclosure Statement

The inclusion of a copy of an International Search Report in the IDS has not been considered because these are non-published documents and can not be properly cited on a 1449 due to lack of a date of publication.

Only the abstracts of DE 4407 079 (B19), DE 19731021 (B25), DE 19856 983 (B26) have been considered.

The information disclosure statement filed March 29 2004, specifically EP 0578998 (B17), fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information,

of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 14, 16 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are vague and indefinite. The claims recite the phrase "less than about". It is unclear if the polymer is capable of absorbing about 5 or less than 5. It unclear what constitutes the upper limit of the absorbing potential of the polymer. The claims recite the phrase "mass % water". It is unclear what that percent is in relationship to. Is it in relationship to the total mass of the total coating or to the biologically degradable polymer (for claims 1, 14, 24) and AB block-copolymer (for claim 16)?

Additionally for claim 1, the claim recites that the first and second polymers "includes". It is unclear what else constitutes the polymers.

Claim 17 recites the limitation "the second polymer" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11, 13-16, 18-24, and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castro et al. (US Patent No. 6395326).

Applicant Claims

A medical article comprising a medical substrate and a coating deposited on the substrate. The medical article is a stent, graft, or stent-graft. The coating comprises a first polymer and a second polymer. The first polymer is poly(ethyleneglycol)-block-co-poly(caprolactone). The second polymer is poly(caprolactone). The medical article additionally includes a therapeutic substance.

A medical article comprising a biologically degradable AB block copolymer and a biologically degradable polymer. The medical article is a stent, graft, or a stent graft. The biologically degradable AB block copolymer is poly(ethyleneglycol)-block-co-poly(caprolactone). The biologically degradable polymer is poly(caprolactone). The article additionally includes a therapeutic agent mixed, bonded, conjugated, linked or blended with the block copolymer and/or the polymer.

A method of treating a disorder in a human comprising implanting in the human a medical article defined above wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

The polymers are capable at equilibrium and at room temperature of absorbing less than 5 mass % water.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Castro et al. is directed to a patterned coating on a prosthesis, for example a stent (abstract). The prosthesis is coated with a composition (column 2, lines 65-66). A therapeutic substance or combinations of substances are included in the composition (column 3, lines 9-11). The polymers listed as being suitable are those that are biocompatible and include polycaprolactone (PCL), PCL-co-PEG, and combinations thereof (column 12, lines 46-67). The form of the polymers include block (column 12, line 33). The therapeutic substance or substances are dispersed in the composition of the polymer (column 13, lines 22-23).

The stent of the invention of Castro et al. is useful for a variety of medical procedures including the treatment of obstructions caused by tumors (column 21, lines 7-16).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Castro et al. does not specify using a combination of polycaprolactone and PCL-co-PEG.

***Finding of Prima Facie Obviousness Rational and Motivation* (MPEP §2142-2143)**

It would have been obvious to one of ordinary skill in the art to pursue known options within his or her technical grasp, specifically the polymers listed in Castro et al. as being suitable for coating a stent, resulting in the practice of the instant application with a reasonable expectation of success.

All of the claimed polymers were known in Castro et al. It would have been obvious to one of ordinary skill in the art to vary the types of polymers used to optimize

the coating, resulting in the practice of the instant application with a reasonable expectation of success.

With regard to the functional limitation pertaining to absorbing less than 5 mass % water, Castro et al. discloses the same claimed polymers. Note MPEP 2112.02 (1I): "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705,709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

With regard to the limitation that the block copolymer be an AB block copolymer. Since the copolymer listed is PCL-co-PEG, this indicates the structure of the polymer is that of AB form, a polymer of caprolactone connected to a polymer of ethylene glycol.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11 and 13-24, and 26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 7229471. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in scope.

The instant application is directed to a medical article comprising a medical substrate and a coating deposited on the substrate. The medical article is a stent, graft, or stent-graft. The coating comprises a first polymer and a second polymer. The first polymer is poly(ethyleneglycol)-block-co-poly(caprolactone). The second polymer is poly(caprolactone). The medical article additionally includes a therapeutic substance.

Patent '471 is directed a medical article comprising an implant and a polymeric material. The implant can be a stent. The polymer can be poly(ethylene glycol), polycaprolactone, copolymers, and combinations thereof. The medical article additionally comprises a plasticizing agent. The plasticizing agent can be selected from the groups consisting of steroids, etc.

All of the claimed polymers of the instant application were also claimed in Patent '471. One of ordinary skill in the could of combined the various polymers, especially since combinations and copolymers are listed as being acceptable, resulting in the practice of the instant application with a reasonable expectation of success.

With regard to the functional limitation pertaining to absorbing less than 5 mass % water, Patent '471 discloses the same claimed polymers. Note MPEP 2112.02 (II): "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705,709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Other Matter

Claims 9 and 22 as written include the phrase "selected from". This phase implies open claim language however a Markush group is a group that is by nature closed. Examiner suggests rewording the claim to include the appropriate language.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail Fisher whose telephone number is 571-270-3502. The examiner can normally be reached on M-Th 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718 or Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 4173

AF

/Cecilia Tsang/

Supervisory Patent Examiner, Art Unit 4173